

DETAILED ACTION

1. Claim 17 has been amended.
Claims 38-52 have been canceled.
2. Claims 17-20, 23-26, 31, and 33-35 are under examination.
3. The following Office Action contains NEW GROUNDS of Rejection.

Objections Withdrawn

4. The objection to claim 51 is withdrawn in view of applicant's cancellation of the claim.

Rejections Withdrawn

5. The rejection of claims 17-20, 23-26, 31, 33-35, 38-50, and 52 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1643

7. Claims 17-20, 23-26, 31, and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for reciting the term "anti-PTHrP (34-53) antibody" in claim 17 because it is unclear whether the term refers to an antibody that binds residues 34-53 of PTHrP or does the term refer to the specific anti-PTHrP antibody obtained from Oncogene as described on page 17 lines 25-27 of the specification.

For the purposes of this office action the term "anti-PTHrP (34-53) antibody" is being interpreted to mean an antibody that binds to residues 34-53 or PTHrP.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 17-20, 23-26, 31, and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon further consideration, the response filed 1/10/2008 has introduced NEW MATTER into the claims. Newly added claim 51 recites that the anti-PTHrP antibody is an anti-PTHrP (34-53) antibody. The response pointed to page 1, lines 33-34, page 27, lines 1-2 and figure 6 and 8 for support of the amended claims. Page 1 lines 33-34

defines biologically active fragments of the PTHrP protein including an amino-terminal fragment (1-36), an intermediate form (38-94/95/101) and a carboxy-terminal form (107-139). Page 27 lines 1-2 defines a specific anti-PTHrP antibody, anti-PTHrP (34-53) Ab-2, obtained from Oncogene and figures 6 and 8 do not define the specific antibodies used for detecting the PTHrP protein regions.

The disclosure of a single species of anti-PTHrP antibody, i.e., the "anti-PTHrP (34-53) antibody" obtained from Oncogene, does not provide adequate written support for the subgenus of anti-PTHrP (34-53) antibodies, i.e., those antibodies that bind residues 34-53 of PTHrP. The as filed specification does not disclose or contemplate antibodies that bind residues 34-53 of PTHrP and such is not adequately conveyed by way of the "anti-PTHrP(34-53) antibody", particularly where the specification defines the intermediate region as residues 38-94/95/101 (e.g., see Fig. 1 and previous claim 50). There is insufficient guidance or direction to lead the skilled artisan from the specific "anti-PTHrP (34-53) antibody" obtained from Oncogene to the broader subgenus of anti-PTHrP (34-53) antibodies that bind residues 34-53 of PTHrP. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

As presently amended, the claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the presently amended claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to

Art Unit: 1643

provide sufficient written support for the limitations recited in present claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 1643

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 16, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643